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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,152	06/03/99	EMALFARB M	3123-4000US2

EXAMINER	
FRONDA, C	
ART UNIT	**PAPER NUMBER**
1652	11

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DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/284,152	Emalfarb et al.
Examiner	**Group Art Unit**
Christian L. Fronda	1652

☒ Responsive to communication(s) filed on *December 29, 2000 (paper no.9)* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-66 and 80-83* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *1* is/are allowed.

☒ Claim(s) *2-66 and 80-83* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. In the **AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111** dated December 29, 2000 (paper no. 9), Applicants have amended claims 67, 68, and 73-76.

Election/Restriction

2. Applicants confirmation of the provisional election with traverse of Group I, claims 1-66 and 80-83, which was made in a telephone interview on August 13, 1999, has been acknowledged.

3. Claims 1-66 and 80-83 are under consideration.

Terminal Disclaimer

4. The terminal disclaimer filed on December 29, 2000, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 5,811,381 and 6,015,707 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-66 and 80-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 4, and 83 are directed to all possible mutant cellulases obtained from the genus *Chrysosporium*. The specification, however, only provides a single representative species encompassed by these claims: a mutant cellulase from a mutant strain of C-1 (see Example 14). There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these mutants by any identifying structural characteristics or properties other than the mutant cellulase having neutral and/or alkaline activity and obtained from a mutant fungus the genus *Chrysosporium* for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 6-66 which depend from claims 2 or 4 are also rejected because they do not correct the defect of claims 2 or 4.

Claims 24, 36, 46, and 52 are directed to all possible nucleic acid sequences from a wild-type or mutant fungus of the genus *Chrysosporium* encoding a cellulase. The specification, however, does not provides a single representative species encompassed by the claim. There is no disclosure of any particular structure to function/activity relationship. The specification also fails to describe representative species of these nucleic acid sequences by any identifying structural characteristics or properties other than the nucleic acid sequence encoding a cellulase used for treating cellulosic fibers or fabrics for which no predictability of structure is apparent. Given this lack of representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 25-29 and 32-35 which depends from claim 26 are also rejected because they do not correct the defect of claim 24. Claims 37-39 which depends from claim 36 is also rejected because they do not correct the defect of claim 36. Claim 47 which depends from claim 46 is also rejected because it does not correct the defect of claim 46. Claim 53 which depends from claim 52 is also rejected because it does not correct the defect of claim 52.

Claims 80-82 are directed toward all possible methods for generating mutant strains of the genus *Chrysosporium*. The specification, however, provides the following representative methods encompassed by the claim: exposure of spores to UV radiation, nitrous acid, N-methyl-N'-nitro-N-nitrosoguanidine, or 4-nitroquinoline-N-oxide. The specification fails to describe additional methods for generating mutant strains of the genus *Chrysosporium*. Given this lack of representative methods as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

7. Claims 2-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant cellulase from a mutant strain of C-1(Example 14) and a cellulase from an isolated culture of *Chrysosporium lucknowense* Garg 27K having accession number VKM F-3500D; does not reasonably provide enablement for any mutant cellulase from any mutant fungus of the genus *Chrysosporium*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any mutant cellulase from any mutant fungus of the genus *Chrysosporium*. The specification provides guidance and examples for making a mutant cellulase from a mutant strain of C-1(Example 14). While molecular biological techniques and genetic manipulation to make the claimed mutant cellulase from a mutant fungus of the genus *Chrysosporium* are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific mutation in the amino acid sequence of the claimed cellulase, i.e. deletion, insertion, substitution, and combinations thereof, which has a neutral and/or alkaline activity is lacking. Thus, searching for the specific amino acid residue(s) of the claimed cellulase to mutate which has neutral and/or alkaline cellulase activity is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine the specific mutation in the amino acid sequence of the claimed cellulase is enormous. Such experimentation entails selecting a species of fungus from the genus *Chrysosporium*, isolating the neutral and/or alkaline cellulase from the selected species, preparing DNA libraries of the selected species, obtaining the DNA sequence encoding the cellulase from screening the DNA libraries, selecting a mutation to perform, i.e. deletion, substitution, insertion, or combinations thereof, mutating the DNA encoding the cellulase, express the mutated DNA encoding the cellulase in host cells, and screening for mutants which have neutral and/or alkaline cellulase activity. Since routine experimentation in the art does not include making and screening vast numbers of mutants for a cellulase having neutral and/or alkaline activity where the expectation of obtaining a desired cellulase having neutral and/or alkaline activity is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific mutation performed on the amino acid sequence of the claimed neutral and/or alkaline cellulase. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 6-66 are also rejected because they do not correct the defect of claims 2 or 4.

8. Claims 80-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for generating mutant strains of the genus *Chrysosporium* with enhanced cellulase activity at neutral and/or alkaline pH by exposing spores to UV radiation, nitrous acid, N-methyl-N'-nitro-N-nitrosoguanidine, or 4-nitroquinoline-N-oxide; does not reasonably provide enablement for any mutagenic method for generating mutant strains of the genus *Chrysosporium* with enhanced cellulase activity at neutral and/or alkaline pH. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The nature and breadth of the claims encompass any mutagenic method including recombinant mutagenic methods for making mutant strains of the genus *Chrysosporium*. The specification provides guidance and examples for making a mutant fungal strains comprising exposing spores to UV irradiation, nitrous acid, N-methyl-N'-nitro-N-nitrosoguanidine, or 4-nitroquinoline-N-oxide. While molecular biological techniques and genetic manipulation to make the claimed mutant fungal strains of the genus *Chrysosporium* are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific mutagenic method for making the claimed fungal strains is lacking. Thus, searching for the specific mutagenic method for making the claimed fungal strains is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine the specific mutagenic method for making the claimed fungal strains is enormous. Such experimentation entails selecting a species of fungus from the genus *Chrysosporium* to mutate, selecting a chemical mutagen out of a vast number of chemicals to apply to the selected species, applying the chemical mutagen to the selected species, and screening for fungal strain mutants out of a vast number of fungal strain mutants that have enhanced levels of neutral and/or alkaline cellulase activity. Alternatively, such experimentation entails selecting a species of fungus from the genus *Chrysosporium* which has cellulase activity at neutral and/or alkaline pH, isolating the neutral and/or alkaline cellulase from the selected species, preparing DNA libraries of the selected species, obtaining the DNA sequence encoding the cellulase from screening the DNA libraries, selecting a mutation to perform, i.e. deletion, substitution, insertion, or combinations thereof, mutating the DNA encoding the cellulase, express the mutated DNA encoding the cellulase in host cells, and screening for mutants fungal strains which have enhanced neutral and/or alkaline cellulase activity. Since routine experimentation in the art does not include making and screening vast numbers of mutant fungal strains having a cellulase with enhanced neutral and/or alkaline activity where the expectation of obtaining a desired cellulase having enhanced neutral and/or alkaline activity is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific mutagenic method used to make the mutant fungal strain having enhanced neutral and/or alkaline cellulase activity. Without such a guidance, the experimentation left to those skilled in the art is undue.

Conclusion

9. Claim 1 is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER